Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
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Preface

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction and Scope

The Food and Drug Administration (FDA) has developed this document to describe the types of information that should be provided in a premarket submission to support a claim of electromagnetic compatibility (EMC) for an electrically-powered medical device. For the purpose of this document, EMC is defined as the ability of a device to function (a) properly in its intended electromagnetic environment, including immunity to electromagnetic disturbance (interference[1]), and (b) without introducing excessive electromagnetic disturbances (emissions) that might interfere with other devices.

Typically, the review of EMC information in a submission is based on the risk associated with EMC malfunction or degradation of the device under review, as well as the use of appropriate FDA-recognized standards or appropriate consensus standards.

Manufacturers of electrically-powered medical devices often reference FDA-recognized consensus national or international standards for EMC, primarily the International Electrotechnical Commission (IEC) 60601-1-2 standard or the equivalent United States (US)

[1] According to International definitions, "disturbance" is the cause and "interference" is the effect. In the US, "interference" is often used interchangeably for both cause and effect though more often for the cause.

version[2] in premarket submissions. In addition, there are device-specific consensus standards, or "particular" standards, under the IEC 60601-1 family (e.g., IEC 60601-2-X, where X denotes a particular device standard). These particular standards may augment or supersede the requirements in the IEC 60601-1-2 standard. There are also other consensus standards for electrically-powered medical devices that include information on EMC (e.g., (International Organization for Standardization (ISO) 14708[3] for active implantable devices).

The items listed below are intended to help ensure that clear and consistent information are provided in premarket submissions regarding medical device EMC, and are consistent with the specifications included in the appropriate standards. Industry and FDA staff should refer to the Center for Devices and Radiological Health (CDRH) Recognized Consensus Standards database[4] for the currently recognized versions of IEC 60601-1-2. The information in this draft guidance is intended to be used in conjunction with other FDA guidance documents[5].

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. EMC Information

To facilitate premarket submissions and reviews, a claim of EMC for a device should be accompanied by the information listed below:

A. a summary of the testing that was performed to support EMC;

B. the specifications of the standard that were met (including immunity test levels);

[2] IEC 60601-1-2: 2007 [3rd Ed.]: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests, IEC 60601-1-2:2014 [4th Ed.], Medical Electrical Equipment, Part 1 2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests, AAMI/ANSI/IEC 60601-1-2: 2007 [3rd Ed.]: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests, and AAMI/ANSI/IEC 60601-1-2: 2014 [4th Ed.]: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests

[3] ISO 14708-3 Implants for surgery -- Active implantable medical devices -- Part 3: Implantable neurostimulators

[4] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[5] Other FDA guidance documents include device-specific guidances such as *Infusion Pumps Total Product Life Cycle* (http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm209337.pdf), cross-cutting guidances such as *Design Considerations for Devices Intended for Home Use* (http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm331681.pdf) and the *Refuse to Accept Policy for 510(k)s* (http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm315014.pdf)

C. the device-specific pass/fail criteria used (this includes how the pass/fail criteria were derived)[6];

D. the specific functions of the device that were tested (e.g., for IEC 60601-1-2, this should include performance that was determined to be essential performance) and how these functions were monitored;

E. the performance of the device during each test, indicating if the device met the emissions and immunity pass/fail criteria;

F. an identification of and a justification for any of the standard's allowances that were used;

G. a description of and justification for any deviations from the specifications of the referenced standard. The justification should explain how the deviations would not compromise the safety and effectiveness (performance) of the device;

H. the device labeling and evidence of compliance with the reference standard's labeling (identification, marking and documents) specifications; and

I. a detailed description of all changes or modifications that were made to the device in order to pass any of the EMC tests. If modifications were made, a statement should be included indicating that the changes or modifications will be incorporated into the final production model and documented in the design history file in accordance with design controls.

Additional information not outlined above may be requested by FDA depending on intended use and intended use environment for specific active medical devices (e.g. implantable portions of active devices) to demonstrate the device's claims regarding electromagnetic compatibility (EMC).

[6] Each medical device should have specific criteria based on the device functions, indications, intended use, and essential performance. Particular device standards (e.g., IEC 60601-2-X) may contain device-specific test methods and pass/fail criteria.